



Docket No.: 000166.2025-US02
(PATENT)

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Henry R. Costantino et al.

Confirmation No.: 8156

Application No.: 10/688,059

Group Art Unit: 1615

Filed: October 17, 2003

Examiner: E. E. Silverman

For: MICROENCAPSULATION AND SUSTAINED
RELEASE OF BIOLOGICALLY ACTIVE
POLYPEPTIDES

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced
Patent Application:

1. Information Disclosure Statement;
2. Form Used in Lieu of PTO/SB/08A/B;
3. Five (5) Non-Patent Literature Documents; and
4. Return Receipt Postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0740, under Order No. 000166.2025-US02. A duplicate copy of this paper is enclosed.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper.

However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740.

Dated: May 25, 2007

Respectfully submitted,

By 

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Registration No.: 36,253

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form Used in Lieu of PTO/SB/08A/B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form Used in Lieu of PTO/SB/08A/B based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any

individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

- ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. 11/541,323, filed September 29, 2006, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a

waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

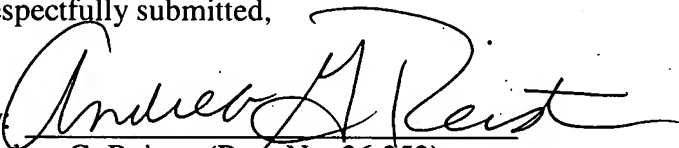
- ☐ 8. In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. Patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).
- ☐ 9. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form Used in Lieu of PTO/SB/08A/B, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740 referencing Docket No. 000166.2025-US02.

Respectfully submitted,

Dated: May 25, 2007

By: 
Andrea G. Reister (Reg. No. 36,253)
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
(202) 662-6000



Used in Lieu of PTO/SB/08A/B
(Based on PTO 04-07 version)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/688,059-Conf. #8156
				Filing Date	October 17, 2003
				First Named Inventor	Henry R. Costantino
				Art Unit	1615
				Examiner Name	E. E. Silverman
Sheet	1	of	1	Attorney Docket Number	000166.2025-US02

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-5,126,147	06-30-1992	Silvestri et al.	
	AB*	US-5,672,659	09-30-1997	Shalaby et al.	
	AC*	US-5,981,719	11-09-1999	Woiszwill et al.	
	AD*	US-6,749,866-A1	06-15-2004	Bernstein et al.	
	AE*	US-20070027085-A1	02-01-2007	Costantino et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (If known)				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Elvassore, Nicola et al., Production of Insulin-Loaded Poly(Ethylene Glycol)/Poly(L-Lactide) (PEG/PLA) Nanoparticles by Gas Antisolvent Techniques, J. of Pharmaceutical Sci., 90(10):1628 (Oct. 2001).	
	CB	Lee and Timesheff, The Stabilization of Proteins by Sucrose, J. Biological Chem, 256(14):7193-7201 (1981).	
	CC	Taylor, K. et al., Continuous Subcutaneous Infusion of AC2993 (Synthetic Exendin-4) Provides Sustained Day-Long Glycemic Control to Patients with Type 2 Diabetes, Diabetes (Suppl 2):A85 (June 2002 Conference ABSTRACT).	
	CD	HAYNES, LIA M. et al. "Neutralizing Anti-F Glycoprotein and Anti-Substance P Antibody Treatment Effectively Reduces Infection and Inflammation Associated with Respiratory Syncytial Virus Infection." Journal of Virology. 76.14 (2002): 6873-6881.	
	CE	KURT-JONES, EVELYN A. et al. "Pattern recognition receptors TLR4 and CD14 mediate response to respiratory syncytial virus". Nature Immunology. 1.5 (2000): 398-401.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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